GE Medical Systems

June 28, 2000

0055 '00 JUL 12 P1:51

Tom Jakub
Chief Diagnostic Branch
CDRH
Mail Stop HFZ-322
2098 Gaither Drive
Rockville, MD 20850

4254 6962 0441

Ref: Variance No. 98V-1233

Mr. Jakub:

This letter is a request for the extension of variance 98V-1233 the has been granted to General Electric Medical Systems, for a period of an additional 6 months, with the extension of the variance to expire December 31, 2000.

As I stated during our phone conversation, Mr. Polizzi is out of the office until sometime in July, so I have attempted to locate the appropriate letters regarding this variance in his files. Enclosed are all that I could locate without Mr. Polizzi's help. The original variance was 96P-0306 and upon extension became the current 98V-1233. If needed, I will contact you with any additional copies of correspondence office regarding these variances as soon as Mr. Polizzi returns.

Hopefully these enclosures will be adequate. Please forward any information regarding this variance to my attention at the above address.

Sincerely,

William A. Gibson
Field Service Compliance Team Leader (FSCT)
Phone: 262-524-5307
Fax: 262-524-5602
E-mail: william.gibson@med.ge.com

Enclosures:
Letter from E. Polizzi requesting an extension of 96P-0306
Letter from E. Polizzi certifying the GE electronic signatures for variance 96P-0306
Original request for variance and first CDRH response

96P-0306

EXP 1

ATTACHMENT #1

GE Medical Systems

OnLine Center

General Electric Company
W25 W22355 Paul Road
Pewaukee, WI 53072

'00 JUL 12 P1:51

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

16 December 1998

Ref: Variance No. 96P-0306 CP1

I, Emanuel V. Polizzi, on behalf of GE Medical Systems hereby request an extension on the above-named variance. This variance is due to expire on 31 Dec. 1998, but to date we have not received information from the Center for Devices and Radiological Health (CDRH) regarding any modifications they might desire to the existing protocols and software which are integral to the variance. We understand that these issues are still under consideration by CDRH, and CDRH has indicated that they require additional experience with the new protocols/software in order to determine the adequacy thereof.

Please advise us on how to proceed. After Thursday Dec. 17 1998, and until January 4, 1999, I will be out of my office, but I will be picking up voicemail, and I will check email.

Thank you,

Emanuel V. Polizzi

Emanuel V. Polizzi W595
Year 2000 Program Coordinator for Service
(414) 524-5323
email: emanuel.polizzi@med.ge.com

c: Gerald E. Vince HFC-100
Tom Jakub HFZ-300
Jim Simpson HFZ-300

ATTACHMENT #2

GE Medical Systems

OnLine Center

General Electric Company
[illegible]
Milwaukee, WI [illegible]

5057 '00 JUL 12 P1:51

Mr. Gerald E. Vince,
Director of Regional Operations
Food and Drug Administration
Office of Regional Operations, HFC-100
Parklawn Building, Room 1361
5600 Fishers Lane
Rockville MD 20857

Dear Mr. Vince;

Ref: Variance No. 96P-0306 CP1

Jim Simpson has advised me that you require certification from GE Medical Systems that the electronic signatures which are part of the electronic version of FDA form 2579, which is covered by the above referenced variance, are legally binding. I've been authorized by our legal counsel to submit the required certification.

Pursuant to Section 11.100 of Title 21 of the code of federal regulations, this is to certify that GE Medical Systems intends that all electronic signatures executed on form FDA 2579 by our employees, agents, or representatives are the legally binding equivalent of traditional hand-written signatures on form FDA 2579.

Please call me at (414) 524-5323 if you need additional information.

Sincerely yours,

Emanuel V. Polizzi

Emanuel V. Polizzi W 595
HHS Support

c: Jim Simpson HFZ 300
Jack O'Malley W 400

ATTACHMENT #3A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

5058 '96 JUL 12 P1:51

August 23, 1996

Emanuel V. Polizzi W595
GE Medical Systems
N25 W23255 Paul Road
Pewaukee, WI 53072

Dear Mr. Polizzi:

Your petition requesting the Food and Drug Administration to amend reporting requirements was received by this office on 08/15/96. It was assigned docket number 96P-0306/CP 1 and it was filed on 08/23/96. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler
Dockets Management Branch

ATTACHMENT #3

August, 5 1996,

5059 '96 JUL 12 P1:51

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

CITIZEN PETITION

I, Emanuel V. Polizzi, on behalf of GE Medical Systems (GEMS), submit this petition under applicable sections of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to amend 21 CFR 1020.30 (d)(1) as described below.

A. Action requested

This amendment is to be effective from October 1, 1996 through December 31, 1996.

Following is the regulation as presently worded, (underlining added for reference):

> "(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of 1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly."

Following is the amended wording requested by this petition, (underlining added for reference):

> "(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under 1010.2 and 1010.3 of this chapter. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly. The assembler shall have the option of submitting paper forms as described in (i) or making electronic submissions as described in (ii).
>
> (i) If the assembler chooses to utilize paper forms for reporting, then the assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of 1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857; or

ATTACHMENT #C

(ii) If the assembler chooses to utilize electronic submissions for reporting, then all information required by the paper form described in (i) shall be included in the electronic submission, in a format, and utilizing security protocols as specified by the Director, Center for Devices and Radiological Health. Paper facsimiles of the completed FDA 2579 forms shall be submitted to the purchaser and, if required, to the relevant State agency. "

B. Statement of grounds

Over the past two years GEMS has developed mainframe and field laptop computer software to facilitate the creation, completion, and tracking of FDA 2579 forms. The software has been in use, in an informal manner, both in the Field and at headquarters since March 1995.

Verification of form content accuracy is the responsibility of the assembler, and final review and approval of the completed form is the responsibility of the assembler's Zone Compliance Engineer; this process has been used by GEMS for many years for processing paper FDA 2579 forms, but has now been improved through electronic data handling. At this time GEMS is capable of providing the FDA with an electronic version of a completed FDA 2579 form in a format we believe to be acceptable to the FDA. In addition, the assembler can print a facsimile of the completed FDA 2579 for the purchaser and for the relevant State agency.

GEMS employs a level of security on its mainframe computer, on its assembler laptop computers, and on the interface which we believe will be consistent with the security requirements surrounding electronic signatures.

Electronic form serial numbers are in the same format as the paper FDA 2579 form serial numbers, but have been programmed so that no electronic form will have the same number as a paper form.

C. Environmental impact

GEMS claims categorical exclusion under 21 CFR 25.24 (e)(3).

D. Economic impact

Information will be provided upon request.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Emanuel V. Polizzi W595
GE Medical Systems
N25 W23255 Paul Road
Pewaukee, WI 53072
(414) 524-5323 FAX (414) 524-5305 e-mail ms06862@msbg.med.ge.com

cc: Tom Jakub HFZ 300, Jim Simpson HFZ 300

GE Medical Systems

OnLine Center

General Electric Company
N25 W23255 Paul Road
Pewaukee, WI 53072

5061 '00 JUL 12 P1:51

16 December 1998

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Ref: Variance No. 96P-0306 CP1

I, Emanuel V. Polizzi, on behalf of GE Medical Systems hereby request an extension on the above-named variance. This variance is due to expire on 31 Dec. 1998, but to date we have not received information from the Center for Devices and Radiological Health (CDRH) regarding any modifications they might desire to the existing protocols and software which are integral to the variance. We understand that these issues are still under consideration by CDRH, and CDRH has indicated that they require additional experience with the new protocols/software in order to determine the adequacy thereof.

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Thank you,

Emanuel V. Polizzi

Emanuel V. Polizzi W595
Year 2000 Program Coordinator for Service
(414) 524-5323
email: emanuel.polizzi@med.ge.com

c:

	Gerald E. Vince	HFC-100
	Tom Jakub	HFZ-300
	Jim Simpson	HFZ-300